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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,638

05/14/2001

John Dapron

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7590

07/31/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/854,638

Applicant(s)

DAPRON ET AL.

Examiner

My-Chau T. Tran

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P r i d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) 39-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-112 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-38, drawn to an assay platform, classified in class 422, subclass 50.
 - II. Claims 39-93, drawn to a method of preparing an assay platform, classified in class 436, subclass 528.
 - III. Claims 94-112, drawn to a polymer composition, classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I (apparatus) and Group II (process) are related as process of making and product (apparatus) made. However, it is noted that the characteristics required for the polymer of Invention II are not the same, as those required for the polymer of Invention I. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product (apparatus) as claimed can be made by a materially different process such as photolithographic technique.

3. Inventions of Group I and Group III are unrelated and independent inventions.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

Art Unit: 1641

806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different functions and effects. The features of the polymer molecule that is attached to the substrate of group I are not required by the claims of Group III. The features of the polymer molecule defined as having a reactive group and a binding ligand of group III are not required by the claims of Group I.

4. Inventions of Group II (process) and Group III (composition) are related as product (composition) and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (composition) as claimed can be used in a materially different process such as chemical vapor deposition to prepare a coated substrate.

5. Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group III would involve a determination of the patentability of the combination of a composition comprised of a reactive group and a binding ligand (independent of its use) while a patentability determination for Group II would involve a consideration of the patentability of the method steps involving in preparing an assay platform. These considerations are very different in nature.

Art Unit: 1641

6. During a telephone conversation with Mr. Kevin Hooper on 4/24/02 a provisional election was made with traverse to prosecute the invention of Group I (Claims 1-38).

Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-112 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) The term “capable of” in Claim 1, 16-23, and 26-28 is vague and indefinite. It is unclear if the polymer matrix or the binding ligand actually does what it is claimed.
- b) The acronym “MALDI” of claim 10 is not defined in the claim so that those who are ordinary skills in the art would know applicant intended meaning.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-9, 12-23, and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bioprobe International, Inc. (WO 92/03732).

Bioprobe teaches an assay platform that has a coating material having a number of functional binding sites available for binding of ligands for use in assay methods involving solid phase materials (pg. 3, lines 28-32; pg. 4, lines 8-29; pg. 6, lines 32-35 to pg. 7, lines 19). The coating comprise a polymer such as dextran (pg. 10, lines 7-21) that a bind to the solid phase materials. The solid phase material is polystyrene microtitre plates. A spacer is also included in order to assist in providing specific binding site for ligand (pg. 7, lines 30-35 to pg. 8, lines 1-2; pg. 8, lines 25-35 to pg. 9, lines 1-26). The ligand is comprised of biological ^{by} active molecules to target molecules such as DNA and RNA (pg. 9, lines 27-35).

Since the polymer matrix of the reference contains all of the features required by the instant assay platform, i.e. the polymer bind to the substrate, the polymers are crosslinked to other polymers and attached to a ligand, it is inherent that the density of the polymer of the reference would also be at least $2 \mu\text{g}/\text{cm}^2$. Therefore, Bioprobe anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1641

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bioprobe International, Inc. (WO 92/03732).

The assay platform of Bioprobe is applied for the reasons stated above.

Bioprobe differs from the claimed invention by failing to include the features such as a glass substrate (Claim 11) and the ligand being a metal chelate (Claim 24).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include these features as elements of the assay platform of Bioprobe because the polymer of Bioprobe can be used in conjunction with solid phase materials with a wide range of ligands in qualitative and quantitative assays (pg. 3, lines 22-26). Further, these features of remaining dependent claims are either well known alternative or constitute obvious

Art Unit: 1641

variations in parameters which are routinely modified in the art (e.g. type of substrate or ligand) and which have not been described as critical to the practice of the invention.

13. Claims 22, 24-25 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bioprobe International, Inc. (WO 92/03732) in view of Döbeli et al. (US Patent 5,047,513).

The assay platform of Bioprobe is applied for the reasons stated above.

Bioprobe differs from the claimed invention by failing to specifically include a metal chelate as the ligand.

Döbeli teaches a metal chelate for chromatography purification of proteins (col. 1, lines 58-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay platform of Bioprobe by including metal chelate as taught by Döbeli because metal chelate^{As}, especially nickel chelate, are known to have a high specificity towards biopolymers such as peptides and proteins (Döbeli: col. 1, lines 30-33 and 42-45; col. 3, lines 48-50). The substitution of the nickel chelate ligand of Döbeli as a ligand in the platform of Bioprobe would constitute a routine choice of a well known ligand, nickel chelate being well known as an agent for protein binding.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999.

The examiner can normally be reached on M-F 8:00-4:30.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
July 25, 2002

Mary E. Ceperley
MARY E. CEPERLEY
PRIMARY EXAMINER
A.U. 1641